

# COMMITTEES

## Ethics Committee

The Ethics Committee considers the ethical implications of all proposed research projects involving human subjects or human tissue to determine whether or not the projects are acceptable on scientific and ethical grounds, in accordance with the NH&MRC *Statement on Human Experimentation and Supplementary Notes*.

It monitors the progress of these research projects annually until completion so as to be satisfied that they continue to conform with the approved ethical standards and that no new ethical issues have arisen. Many of the projects extend over several years, as they try and tackle complex, difficult research questions. During this year, four new projects were submitted; three were approved without modification, and one required amendment. Three projects were completed, resulting in 28 on-going projects.

This year we welcomed to the committee Mr Brian Stevenson, Deputy Principal of The University High School, in the category of community representative.

Of the projects reviewed this year, we report briefly on two major fields of research.

### 1. The Malaria Vaccine Project

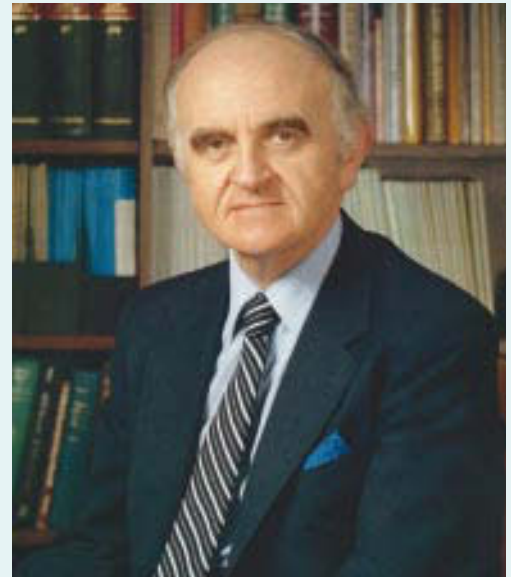
Following phase 1 safety trials of a combination vaccine in healthy adult Australian volunteers and then in adults in Papua New Guinea, undertaken in 1996, the committee was asked to comment on the protocol for this same vaccine to be tested in healthy PNG children of 5–10 years of age.

Several ethics committees are involved in this project as it moves into clinical trials. The committee of the Queensland Institute of Medical Research and the Hall Institute's committee continue to receive all protocols, but final approval rests with the ethics committee of The Papua New Guinea Institute of Medical Research.

As it does with all projects, the committee evaluated carefully the method of subject recruitment, selection and the translation of the information provided in the plain language statement.

The committee also considered the length of the period of monitoring for any adverse effects. In addition to the trial monitors, there is also an independent monitor.

While this trial is proceeding, another test vaccine candidate is being formulated, with plans to go to safety trials. Again several ethics committees will review trial protocols, including the



*Professor Louis Waller AO*

WHO ethics committee, which is funding the development of this vaccine candidate.

### 2. Human genetic research

During the year the committee has reviewed several projects where the goal is the search for genes linked to serious diseases or human conditions. Genetic linkage is an essential step in the process of finding disease-susceptibility genes.

A number of important ethical issues arise in human genetic research. Genetic information related to one subject may have implications for other family members. This raises questions about privacy and confidentiality. Are subjects able to refuse to receive information, and if so, what impact would this have on disclosure to others? The availability of counselling support in all genetic projects has also been discussed.

Other issues, such as the possible effect on employment or life insurance, have also been raised. The relationship between research, goals and possible societal consequences is complex in this emerging, important field.

The committee is introducing new draft guidelines on genetic research for researchers, pending the development of national guidelines by the NH&MRC.

*Professor Louis Waller AO  
Chair, Institute Ethics Committee*

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